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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/722,544	11/28/2000	Hong Chen	07334-362001 / MPI98-033P	6903

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EXAMINER	
WILDER, CYNTHIA B	

ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 03/31/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/722,544	Applicant(s) CHEN et al.
	Examiner Cynthia B Wilder	Art Unit 1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jan 27, 2003* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1 and 19-31* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1 and 19-31* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Applicant's amendment filed in Paper No. 19 is acknowledged. Claims 1, 19, and 21-31 have been amended. Claims 1, 19-31 are pending. All of the amendments and arguments have been throughly reviewed and considered but are deemed moot in view of the new grounds of rejections. rejections not reiterated in this action have been withdrawn as being obviated by the amendment of the claims.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Previous Objections and Rejections

3. The objections to the specification is withdrawn in view of Applicant's amendment to the specification. The claim rejection under 112 First paragraph as lacking deposit requirement is withdrawn in view of Applicant's amendment and statement regarding Budapest Treaty deposit. The claim rejections under 35 USC 112 second paragraph are withdrawn in view of Applicant's amendment to the claims.

New Ground(s) of Rejections

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1, 19-31 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such as way as to enable one skilled in the art to which it pertains, or with which is most nearly connected, to make and/or use the invention. Specifically, the claims are directed to a method for identifying an individual having or at risk of developing a bipolar affective disorder or schizophrenia comprising the step of detecting the presence or absence of a HKNG1 gene product in a patient sample wherein said method comprises the steps of (a) incubating a sample in the presence of a detectably labeled antibody; and (b) assaying for the presence of a human HKNG1 gene product. The claims also recite that the assay step comprises and immunoassay, more specifically, an ELISA. The claims recite that the HKNG1 gene product is detected in cerebrospinal fluid and the HKNG1 product is conserved variant or peptide fragment. The claims recite that the HKNG gene product comprises an amino acid sequence which is different from the amino acid sequence depict in SEQ ID NO: 2.

The specification teaches that the HKNG1 gene is associated with human neuropsychiatric disorders, such as schizophrenia and bipolar affective disorder (BAD) (pg 6). The specification teaches that antibodies directed against unimpaired or mutant HKNG1 gene products or conserved variants or peptide fragments may be used as diagnostics and prognostics for a HKNG1-mediated neuropsychiatric disorder, such as BAD or schizophrenia (page 43, lines 17-21). The specification discloses that immunoassays for HKNG1 gene products will typically comprise incubating a sample in the presence of a detectably labeled antibody by any of a number of techniques known in the art, such as by ELISA (page 45, lines 28-32 through page 46). However, this is not adequate guidance,

but is merely an invitation for the artisan to use the current invention as a starting point for further experimentation. For example, the specification does not teach any methods or working examples that indicate an individual can be identified as having or at risk of developing BAD or schizophrenia by incubating a sample in the presence of a detectably labeled antibody and assay for the presence of all possible HKNG1 gene products. Undue experimentation would be required of the skilled artisan to determine which specific HKNG1 gene product to assay for, particularly since the wild-type HKNG1 gene is expressed in normal tissues in non-diseased subjects and there is more than one polymorphism of HKNG1 associated with BAD and schizophrenia (page 90, Figure 5). Furthermore, the claims also recite the step of detecting/assaying the presence or absence of a HKNG1 gene product. However, as discussed above, the specification discloses that the HKNG1 gene products (wild-type and mutants) are always present in the subject samples (page 88-90). There is no guidance in the specification teaching the skilled artisan how to detect the absence of a HKNG1 product since the gene product (wild-type and mutant) is constantly present in the subject sample. Additionally, the specification does not teach that an aberrant level of any HKNG1 gene product (wild-type or mutant) is associated with an individual having or at risk of developing BAD or schizophrenia. Therefore, undue experimentation would be required of the skilled artisan to measure the levels of all possible HKNG1 gene products in normal, "affected" and "at risk" subjects and correlate these levels with BAD and schizophrenia.

Furthermore, Applicant has provided little or no guidance beyond the mere presentation of "control" and "affected" subject populations to enable one of ordinary skill in the art to identify,

without undue experimentation, individuals "at risk" of developing BAD or schizophrenia via the claimed methods. A large quantity of experimentation would be required by the skilled artisan to determine which subjects to sample and monitor over a period of years. For example, how would the subjects be selected? At what age would the sampling begin/end? On average, how many years would be required to determine whether or not the subject develops BAD or schizophrenia? Such trial and error is considered undue and according to MPEP 2164.06, "the guidance and ease in carrying out an assay to achieve the claimed objectives may be an issue to be considered in determining the quantity of experimentation needed".

Due to the large quantity of experimentation necessary to determine the presence of all possible HKNG1 gene products in a subject, to assay for the absence of any HKNG1 gene product, to measure the aberrant level of any HKNG1 gene product, and to identify individuals "at risk" of developing BAD or schizophrenia, the lack of direction/guidance presented in the specification regarding the same, the absence of working examples directed to the same, the complex nature of the invention, and the breadth of the claims which fail to recite more specific HKNG1 gene products, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention its full scope.

Double Patenting

6. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful

process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

7. Claims 1, 19-21, 23, 26-27 and 29 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1, 19-21, 23, 26-27 and 29 of copending application 09/691,064. This a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Conclusion

8. No claims are allowed. However the claims are free of the prior art.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Cynthia Wilder whose telephone number is (703) 305-1680. The examiner can normally be reached on Monday through Thursday from 9:30 am to 6:30 pm and on Friday from 9:30 am to 1:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached at (703) 308-1119. The official fax phone number for the Group is (703) 308-4242. The unofficial fax number is (703) 308-8724.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Group's receptionist at (703) 308-0196.

Cynthia B. Wilder

cbw
March 28, 2003

Cynthia B. Wilder, Ph.D.
Patent Examiner
Art Unit 1637